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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942.596	08/31/2001	Nobuko Yamamoto	35.C15718	7458

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1634	11

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,596	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7, 9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Sequence Rules

1. The current case complies with the Sequence rules and the sequences were entered by the Scientific and Technical Information Center.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (Science (1996) 274:610-614)

Lockhart teaches a method for identifying an unknown base sequence present in a target single stranded nucleic acid (see abstract) comprising the steps:

(a) preparing a probe array in which single stranded nucleic acid probes are arranged as isolated spots on a substrate, the probes each having a base sequence complementary to one of plural base sequences expected to be the unknown base sequence (see page 610, column 2 to page 611, column 1),

(b) reacting a single stranded nucleic acid, which has a base sequence fully complementary to a base sequence of one of the single stranded nucleic acid probes

and is fluorescence labeled with the probe array under conditions that single stranded nucleic acids complementary to each other form a double stranded nucleic acid (see figure 1, panel C, top array and page 613, note 12)

removing the unreacted labeled single stranded nucleic acid (see page 613, note 12 and note 13),

measuring fluorescence intensity of each spot of the probe array to obtain a first template pattern showing a relationship between location of the probes and fluorescence characteristics (see page 614, notes 15, 17 and 21)

(c) performing the same operation as the step (b) for each of the remaining single stranded nucleic acid probes and obtaining template patterns of each probe showing a relationship between location and fluorescent characteristics of the probes (see figure 1, panel C, top array, and pages 613 and 614),

(d) performing the same operation as step (b) using a sample containing the target single-stranded nucleic acid of unknown base sequence to obtain a sample pattern showing relationship between a position and fluorescent characteristic (see figure 1, panel C, bottom array and pages 613 and 614)

(e) comparing the sample pattern obtained in step (d) with n pieces of template patterns obtained in steps (b) and (c), to identify a template pattern showing substantially the same pattern as the sample pattern and identifying the base sequence of the single stranded nucleic acid used from the preparation of the identified template pattern as the unknown base sequence of the target single stranded nucleic acid (see page 611, figure 1 and column 1 and page 612, figure 2 and columns 1-3, where Chee

expressly notes "The array was used to successfully detect three disease causing mutations in a mtDNA sample from a patient with Leber's hereditary optical neuropathy. In addition, we detected a total of seven errors and new polymorphisms from previously unsequenced regions (see page 612, column 3).")

(f) Chee further analyzed the probe arrays to calculate a mean value of fluorescent intensities (see page 614, note 18) and then a difference was calculated between the fluorescence intensity of a reference array without a mismatch and the mean value of fluorescent intensities of the double stranded nucleic acids having a one or greater base mismatch (see page 614, note 16 and page 611, column 3) and

(g) Chee expressly notes regarding comparison of one and two mismatches to a control that "The marked decrease in target hybridization intensity, over a span of 20 nucleotides, is shown for a single base polymorphism as position 16,223 (Fig. 2A). The footprint is enlarged when two polymorphisms occur in close proximity (within 20 nucleotides) (Fig. 2B).(see pge 611, column 2)". Chee analyzes each of the positions to show a relationship between location and the fluorescent characteristics of the probes (see page 614, note 16 and page 611, column 3 and figure 2).

(h) Chee compares the sample pattern obtained from the unknown with the known sample pattern to identify the base sequence (see page 612, column 3 and page 614, notes 16 and 18).

Chee determines a two valued pattern using two colors (see figure 2) and has a threshold intensity value (see page 614, note 18, where at least 50 counts above background is required).

Chee teaches probes in the range from 15 nucleotide oligomers (see page 610, column 3).

Chee teaches single base pair mismatch detection (see figure 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

March 4, 2003